

**REMARKS**

As an initial matter, there appears to be some confusion regarding the currently elected claims. In the previous Restriction Requirement, the Examiner grouped Claims 1-28 in one of four groups (Groups I-IV). Claims 29-32, which were added by Preliminary Amendment on January 6, 2005, were not mentioned in the Restriction Requirement and thus not grouped into one of the four groups. The undersigned also failed to mention these claims in the Response to the Restriction Requirement filed October 12, 2007.

Of these omitted claims, Claims 31 and 32 depend directly or indirectly from Claim 26, which was part of Group II elected by Applicants in their Response to the Restriction Requirement. As such, Applicants assume that Claims 31 and 32 were meant to be included in Group II. Thus, Applicants understand that Claims 11-22, 26, 31, and 32 have been elected and the present listing of claims proceeds on that understanding. Additionally, the Restriction Requirement contained an election of species. Applicants' election of species resulted in Claims 11, 12, 14, and 19-22 reading on the elected species (as stated in Applicants' response to the Restriction Requirement). This is still believed to be correct, even in light of the new claims presented herewith.

**Amendments to the Claims**

Claim 11 has been rewritten in independent form. Claims 22 and 26 have been amended for clarity. New Claims 33-38 have been added. Support for new Claims 33 can be found in the specification at page 15 (3<sup>rd</sup> structure). Support for new Claim 34 can be found in the specification at page 14 (3<sup>rd</sup> structure). Support for new Claims 35 and 36 can be found in the specification at page 14 (2<sup>nd</sup> structure) and page 13, lines 11 and 15. Support for new Claim 37 can be found in the specification at page 21, line 2. Support for new Claim 38 can be found in the specification at page 19 (first three structures).

No new matter is believed to have been added by these amendments; therefore, examination is requested on the claims as amended herewith. Additional claim fees in the amount of \$300.00 is enclosed herewith to cover new Claims 33-38 (6 x \$50.00).

Claims 1-38 are pending. Claims 11-22, 26, 31, and 32 were elected. Claims 11, 12, 14, and 19-22 read on the elected species and are under examination.

**Rejections under 35 USC § 102**

In the Office Action, Claim 11 was rejected as allegedly being anticipated by EP 0837084 to Bennett *et al.* Specifically, the Office Action asserted that Bennett *et al.* discloses biodegradable, biocompatible branched polymers containing dioxane units that are optionally end-capped with isocyanate. The Office Action further contended that these isocyanate end-capped polymers are formed by the reaction of an isocyanate with a low molecular weight multifunctional core, and in this regard, refers to Example 9 of Bennett *et al.* Applicants respectfully traverse this rejection.

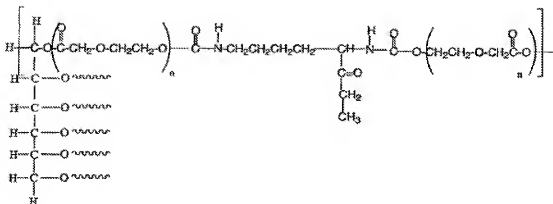
Notably, the species with which the isocyanate is reacted in Example 9 is not a low molecular weight multifunctional core within the meaning of the nomenclature as used in the present application. In Example 9 of Bennett *et al.*, the isocyanate is reacted with a star copolymer of p-dioxanone and glycolide utilizing a pentaerythritol core (p. 4, ll. 24-25, describes the pentaerythritol as a “polyhydric alcohol initiator [that] is employed to provide a highly branched or star structure”).

Claim 11 of the present application recites a prepolymer comprising the reaction product of isocyanate and low molecular weight multifunctional core molecules. Examples of low molecular weight multifunctional core molecules are given on page 13, lines 10-23, with pentaerythritol being stated.

Therefore, Claim 11 is distinguishable from Bennett *et al.* because it recites isocyanate reacted **directly** with a multifunctional **core molecule**, whereas Bennett *et al.* discloses that the isocyanate is reacted with a polymer or copolymer formed from the reaction between a core molecule and **further monomers**.

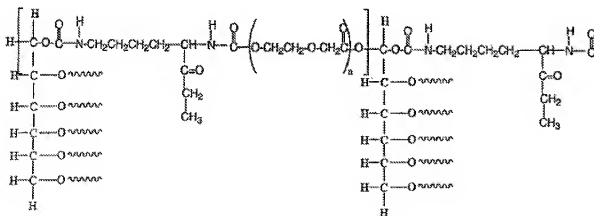
This clear difference in the synthesis chemistry results in key structural differences between the products. In the claims, the urethane linkages formed through the reaction of isocyanate with the core molecule, are **close to the core** as is illustrated in Scheme 1 on page 17 of the present application. Contrastingly, in Bennett *et al.* the isocyanate is used to end-cap a polymer or copolymer. These difference can be further illustrated by the two Structures below.

Structure 1



Structure 1 reflects the class of product produced by Example 9 of Bennett *et al.* The diisocyanate has reacted with a star copolymer so as to cap the star copolymer. The  $-(C=O)-N-$  moiety on the left hand side of the structure is directly bound to a polymeric core, as evidenced by the  $n$  suffix on that core.

Structure 2



Contrastingly, in Structure 2, the diisocyanate has reacted with a low molecular weight multifunctional core. In this case, the  $-(C=O)-N(H)-$  moiety on the left hand side of the structure is directly bound to the low molecular weight core and there is no n suffix present.

### **Rejections under 35 USC § 103**

The major advantage of the prepolymers and polymeric compositions of the invention resides in their ability to be delivered *in vivo* in an injectable, flowable state, and then to harden into a biocompatible, biodegradable scaffold or other device. It is necessary to their functionality that they not harden before delivery (unless so desired) and that *in situ*, they have no toxicity which might mitigate against their ability to support medical treatment of a patient.

The Office Action rejected Claims 12, 14, 19-22 as allegedly being unpatentable over Bennett *et al.* in view of US Patent 3,281,378 to Garber *et al.*

As has been established in respect of the objection under 35 USC § 102, Bennett *et al.* fails to disclose chemical structures that destroy the novelty of the present claims. Additionally Bennett *et al.* is silent with respect to flowable and injectable compositions.

The Office Action has cited Examples 17, 19 and 36 of Garber *et al.* as exemplifying reactions of pentaerythritol with various diisocyanates. The Examples all utilize organic solvents such as xylene, ethyl acetate, kerosene, petroleum benzin, or toluene for the reactions. The solvent is used to provide a vehicle for performing the reactions and to further provide a flowable final reaction solution. Column 3, lines 31-32, states that the reactions are carried out preferably in a solvent solution.

Accordingly, Garber *et al.* specifically discloses the preference for using an organic solvent and teaches away from the absence of solvent. There is no teaching that the products of the reactions could be injectable or flowable, in the absence of solvent.

The claims in question all recite the use of a "flowable prepolymer," which is used to form a biocompatible composition. As organic solvents such as those recommended by Garber *et al.* are toxic, biocompatibility requires the absence of organic solvents during the synthesis. Accordingly, there is no teaching in Garber *et al.* that would lead the skilled artisan to eliminate the solvents of Garber *et al.* with any expectation of achieving the product flowability recited in the claims.

**Other matters**

When asserting the previous Restriction Requirement, the Examiner argued that Groups II-IV had a common technical feature but that the feature was not a special technical feature because the composition was anticipated by WO 9902168 to Cohen *et al.* The Examiner also stated that since the alleged separate inventions did not contribute a special technical feature when viewed over the prior art they did not have a general inventive concept and so lacked unity of invention.

For the sake of completeness, in respect of Cohn *et al.*, Applicants note that this specification discloses biodegradable AB block copolymers that are further reacted with one or more coupling agents or cross-linking agents to produce di-block, multi-block, star-like polymers, and comb-like polymers. The coupling agent could be a diisocyanate; however, the compositions described are polyesters and are not in the same chemical class (polyurethane/ureas) as the compositions recited in the present claims, despite the use of diisocyanates as coupling agents. Cohn *et al.*'s polymers are structurally different to those of the instant claims. It is also unlikely that the polymers of Cohn *et al.* are injectable.

**CONCLUSION**

In light of the foregoing amendments and remarks, it is believed that the rejections presented in the Office Action have been overcome. Accordingly, Applicants respectfully submit that the Application is allowable and seek notification of same.

Payment in the amount of \$300.00 is enclosed herewith for the additional claim fees. No further fees are believed to be due; however, the Commissioner is hereby authorized to charge any fees which may be required or credit any overpayment to Deposit Account No. 14-0629.

ATTORNEY DOCKET NO. 23292.0003U1  
APPLICATION NO. 10/520,414

Respectfully submitted,  
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/Christopher L. Curfman/

February 29, 2008

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Date